



Cal Bionics

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Summary of Safety and Effectiveness for Contact Lens with Color Additive.

The material from which the lens will be manufactured is FDA approved methafilcon-A. When fully hydrated, the material has a 55% water content. This high water content soft (hydrophilic) contact lens material has been tested for performance, comfort and oxygen transmissibility. Since 1984, it has been a widely employed polymer in the contact lens industry. There are many FDA approved manufacturers of soft contact lenses from this material.

Cal Bionics, Inc. received FDA Approval for our daily wear and extended wear soft contact lenses in 1986. In the ten years that our FDA approved daily wear and extended wear lenses have been distributed, there have been no reported adverse reactions or significant complaints. Cal Bionics, Inc. manufactures the contact lens blanks which are then supplied to our FDA approved Alternate Manufacturing Sites where the blanks are lathe cut into finished soft contact lenses.

We now intend to add a "visibility tint" to our daily wear lenses so that they can be seen more easily while being handled for cleaning. We intend to add to our contact lens blanks a small amount of a colorant approved by the FDA for use in contact lenses. The concentration of the colorant is within the range approved by the FDA for use of this colorant in lenses. The colorant concentration is so low that the finished contact lens appears to have just a very faint blue-green tint when held against a white background. The very faint tint of this lens does not change the apparent color of the wearer's eye.

The processes and equipment used to manufacture the "visibility tint" blanks and lenses are identical to those used for our clear daily wear blanks and lenses. The addition of the colorant does not affect the material in any way except for the addition of a faint color. The cleaning regimens already approved by the FDA for our clear lenses will apply to the tinted lenses. The parameters and indications for the tinted lenses are exactly the same as those approved by the FDA for our clear lenses.

It is believed that the addition of an FDA approved colorant, in concentrations approved by the FDA, to an FDA approved polymer will produce tinted lens blanks which will produce the safest of conditions when manufactured into soft (hydrophilic) contact lenses following these designs and parameters already approved by the FDA.

This summary of 510(k) safety and effectiveness is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.